

Focus on Phase 2 FSMA Implementation

<http://www.fda.gov/fsma>

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

FSMA: The Goal

Why FSMA?

Too many preventable food related illnesses / deaths

Role of FDA Policy Makers

Establish prevention oriented standards from farm through distribution of food to retail based on sound science, risk

Role FDA/State Food Safety Regulatory Staff

Gain industry compliance with new standards

Role of Regulator Training/Curriculum Development

Well trained, knowledgeable inspectorate to perform inspections in a uniform manner, consistent decision making

Presentation Overview

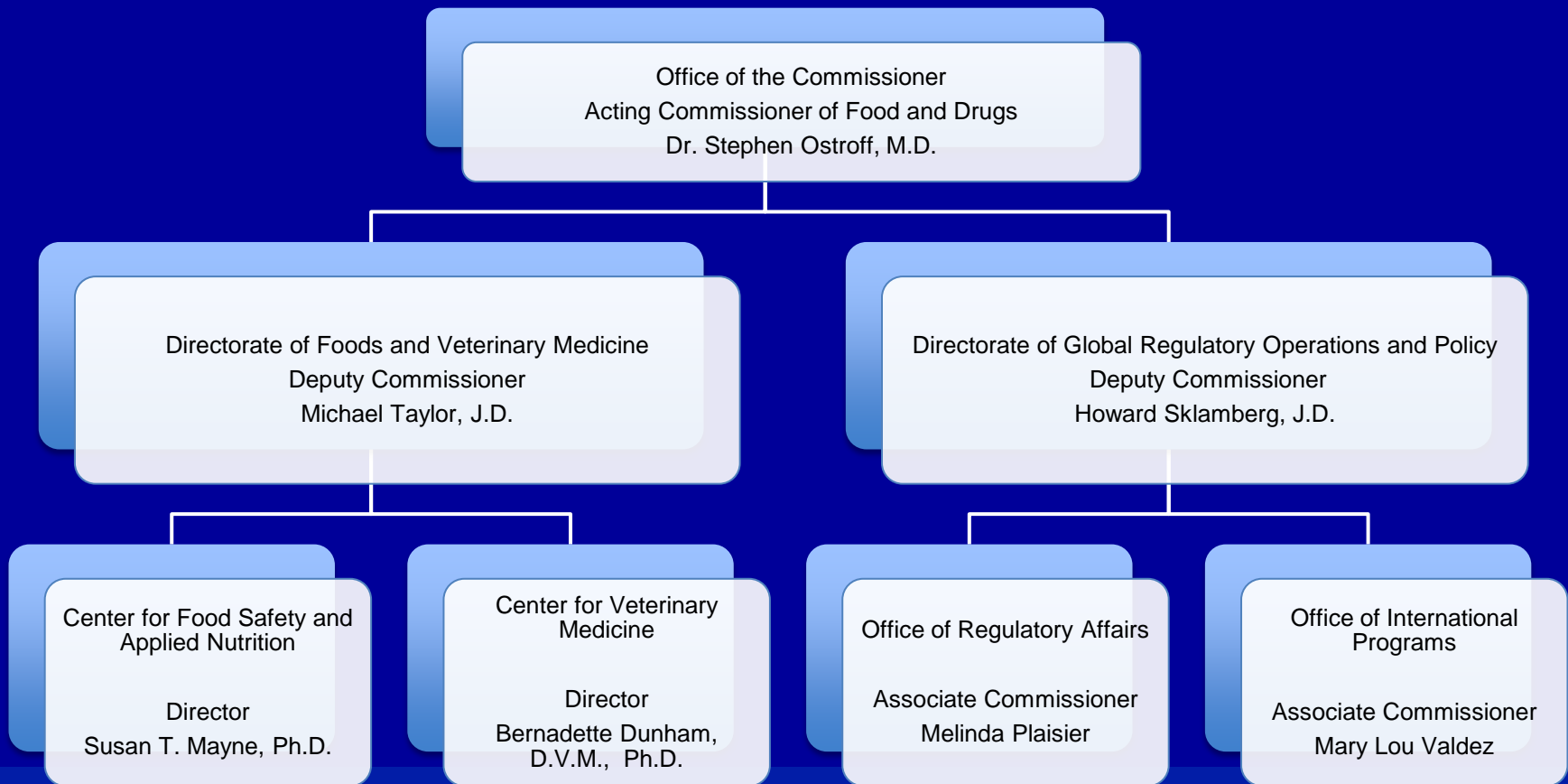
FSMA Implementation

IMPLEMENTATION

- Rulemaking and Industry Guidance
- Gaining and Maintaining Industry Compliance with the Rules
 - FSMA Implementation Guiding Principles
 - Industry Training /Technical Assistance
 - Regulator Training /Technical Assistance
 - Inspection and Compliance/Enforcement
 - Accountability and Stakeholder Engagement
- Performance Measures

FDA's Food/Feed Program

Spans Two Directorates and Four Offices/Centers



FSMA Implementation

“A Continuum”

IMPLEMENTATION

- **Phase 1: Set Standards**
Develop regulations, guidance, policy
- **Phase 2: Design Strategies to Promote and Oversee Industry Compliance**
Identify performance metrics to measure success
- **Phase 3: Implement, Monitor, Evaluate, Refresh**
Transition strategies and performance metrics from design to operational, evaluate success

Phase 1: Standard Setting

Regulation	Proposal	Final (consent decree)
Preventive Controls (Human Food)*	Jan 16, 2013	Aug 30, 2015 Sept 17, 2015 [◇]
Preventive Controls (Animal Food)*	Oct 29, 2013	Aug 30, 2015 Sept 17, 2015 [◇]
Produce Safety*	Jan 16, 2013	Oct 31, 2015
Foreign Supplier Verification Program*	Jul 29, 2013	Oct 31, 2015
Third Party Accreditation	Jul 29, 2013	Oct 31, 2015
Sanitary Transport	Feb 5, 2014	Mar 31, 2016
Intentional Adulteration	Dec 24, 2013	May 31, 2016

**Supplemental proposals published September 2014*

◇ Final rule publication date

Phase 2 FSMA Implementation

*Gaining and Maintaining Industry Compliance
with FSMA Final Rules*

Phase 2: Operations and Policy Working Together

IMPLEMENTATION

High-level FDA Oversight
FVM Governance Board
FVM Executive Council



Steering Committee



Intentional
Adulteration

Import Controls

Preventive Controls
Human Food
Animal Food

Produce Safety



Sanitary
Transportation

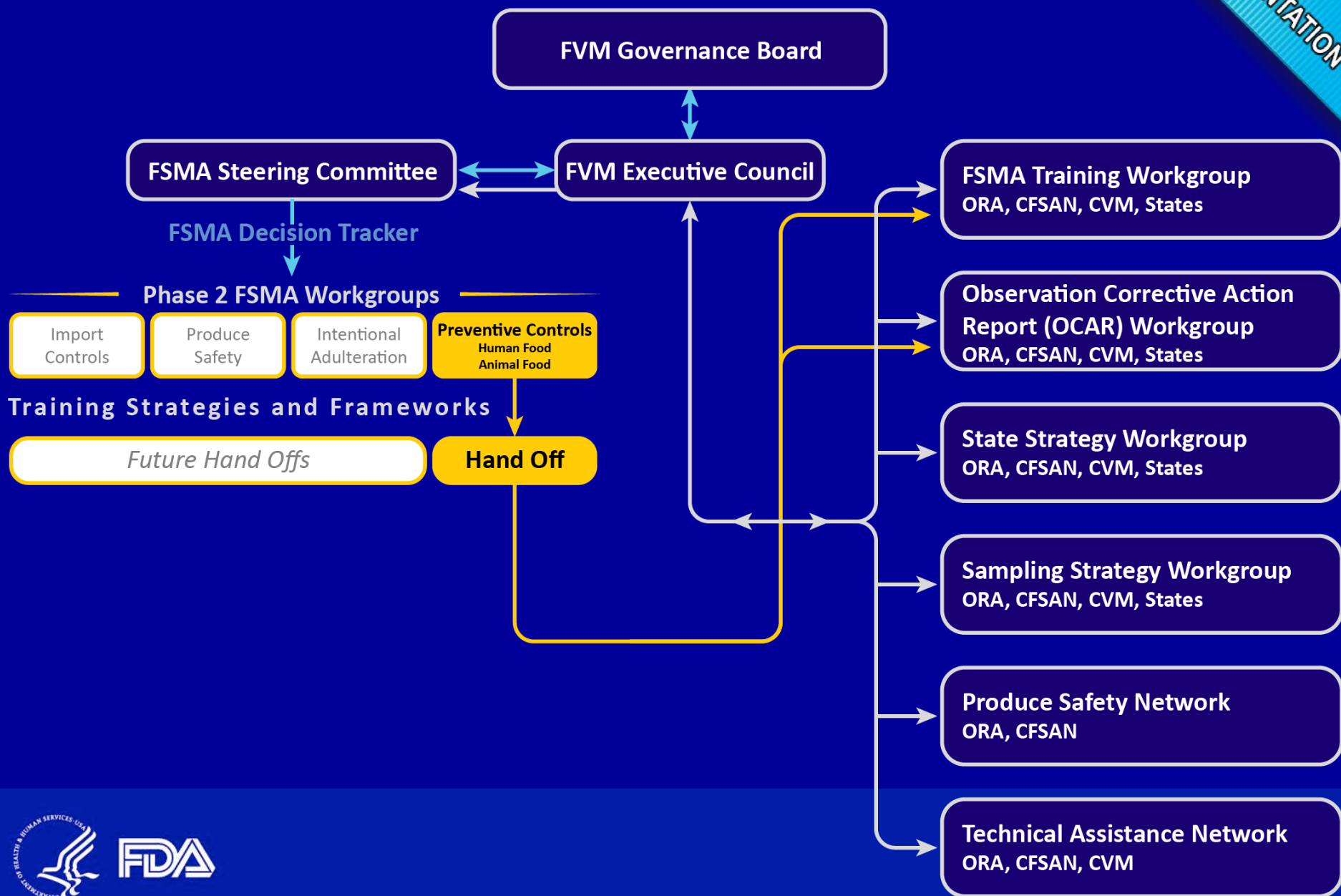
Sprout Safety

ORA, CFSAN, CVM and
State Representation



IMPLEMENTATION

FSMA Workgroups Established by FVM Executive Council



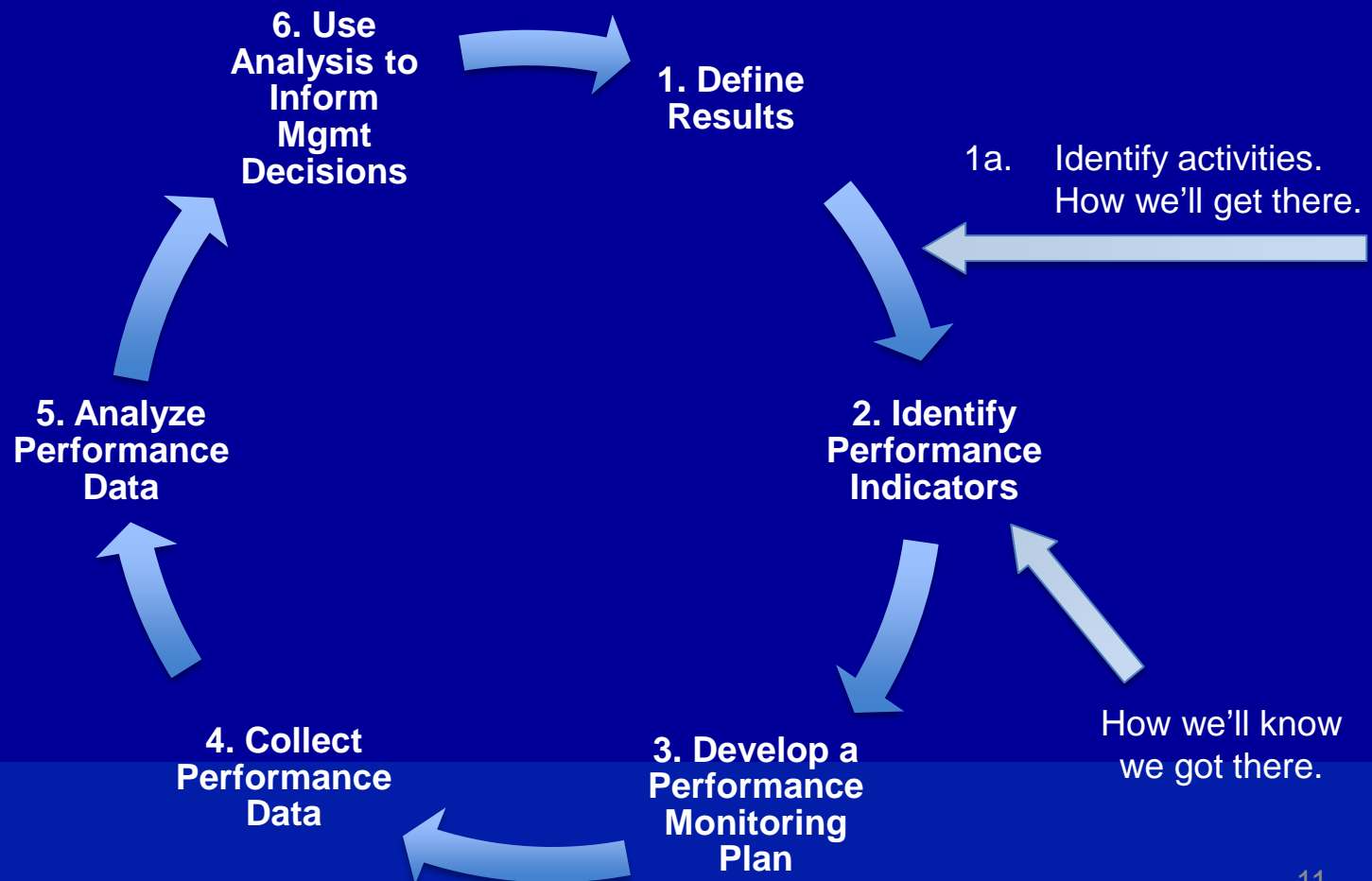
Phase 2 Charge to Workgroups

Develop a framework and multi-year implementation plan for ensuring compliance with regulations:

- Education, outreach and technical assistance for industry
 - Alliances
- Training for regulators
- Data collection, analysis, updated IT
- Performance goals and metrics
- Inspections, compliance and enforcement

Strategic Program Planning (ROM System): 6 STEPS

IMPLEMENTATION



Reduced Risk of Illness Attributed to Food
From Facilities Subject to the PC Rule

1: More Rapid and Effective Recall
Actions by Facilities Subject to PC Rule

2: Reduced Contamination of Food
From Facilities Subject to PC Rule

3: Increased Implementation by
Industry of PC Rule Requirements

Key Results
Industry
Regulatory

4: Increased
Transparency/Info
Exchange Related
to PC Rule for
Emerging Issues
Between Regulatory
Agencies, Public
Health Orgs &
Industry

5: Increased
Acceptance by
Firms of their
Responsibility for
Meeting PC
Standards (for
Food Safety)

6: Expanded
non-
Enforcement
Incentives

7: Increased Industry
Understanding of PC Rule and
the Underlying Science

8: More Effective
and Efficient
Regulatory
Activities Related to
the PC Rule

5.1: Increased Availability
of PC Training, Guidance
Materials, and Technical
Assistance for Food Safety
Staff and Industry (learning
resources)

8.1: Increased
Knowledge by Food
Safety Staff of PC
Rule & Underlying
Science

8.2: More Effective
Inspection &
Enforcement
Program/ Protocol
Established

8.3: Expanded
Risk-Based
Management of
Regulatory
Resources

8.3.1: Increased Capture, Analysis,
Management, & Sharing of Enforcement
Relevant Information

8.3.2: Improved
Analytics to Assess
Risk

A: Improved and
Integrated IT
Infrastructure and
Systems

B: Increased
Availability of
Information based on
US Safety Standards

C: Improved
Collaboration and
Integration Between
FDA and Regulatory
Partners

D: Improved
Coordination and
Information Sharing
between FDA Offices

E: Research
Better Targeted to
PC Priorities

Guiding Phase 2 FSMA Implementation

Program Alignment

- Program Alignment Initiative Announced in February 2014 Memo by Commissioner
 - Vertically integrated, commodity-based programs
 - Specialization of inspection/compliance staff, regulatory labs
 - Clear, current, consistently applied policy
 - Roles, responsibilities, streamlined decision-making
 - Risk-based allocation of program resources
 - Agreed-upon performance/public health metrics

Result: Successful FSMA Implementation



Guiding Phase 2 FSMA Implementation

FDA's FSMA Operational Strategy Document

- Made Public May 2014
 - View at fda.gov/fsma
- Foundation for Developing and Implementing FSMA Standards
 - Regulations, guidance, protocols
- Captures in Broad, High-Level Terms our Current Thinking on Strategy and Guiding Principles for Implementation

Key Implementation Principles

Industry Education, Outreach, Technical Assistance

- Facilitate industry compliance with prevention oriented standards through: guidance, developing tools/resources for education, outreach and technical assistance
 - *Guidance Documents*
 - *Alliances*
 - *Technical Assistance Networks*

Key Implementation Principles

Regulator Training

- Invest in regulator training/continuing education to promote uniform, quality inspections resulting in consistent decision making
 - FSMA Chats
 - Industry Best Practices Webinars
 - Alliance Courses with Industry
 - Regulator Training
 - Technical Knowledge
 - Inspection Skills and Knowledge
 - Behavior and Systems Thinking
 - Support/Mentors and TAN

Key Implementation Principles

Inspections

- Gain industry compliance, reduce foodborne illness
- Not a “one size fits all approach”
- Systems-based inspections, not “observation focused”
- Interactive, cooperative inspections

Key Implementation Principles

Compliance and Enforcement

- Develop and implement explicit inspection/enforcement strategies that facilitate consistent decision making by regulators
- Encourage industry to comply and make corrections on its own
- Recognition that not all observations are equal relative to risk and potential for public health impact
- Regulatory strategy that is dynamic

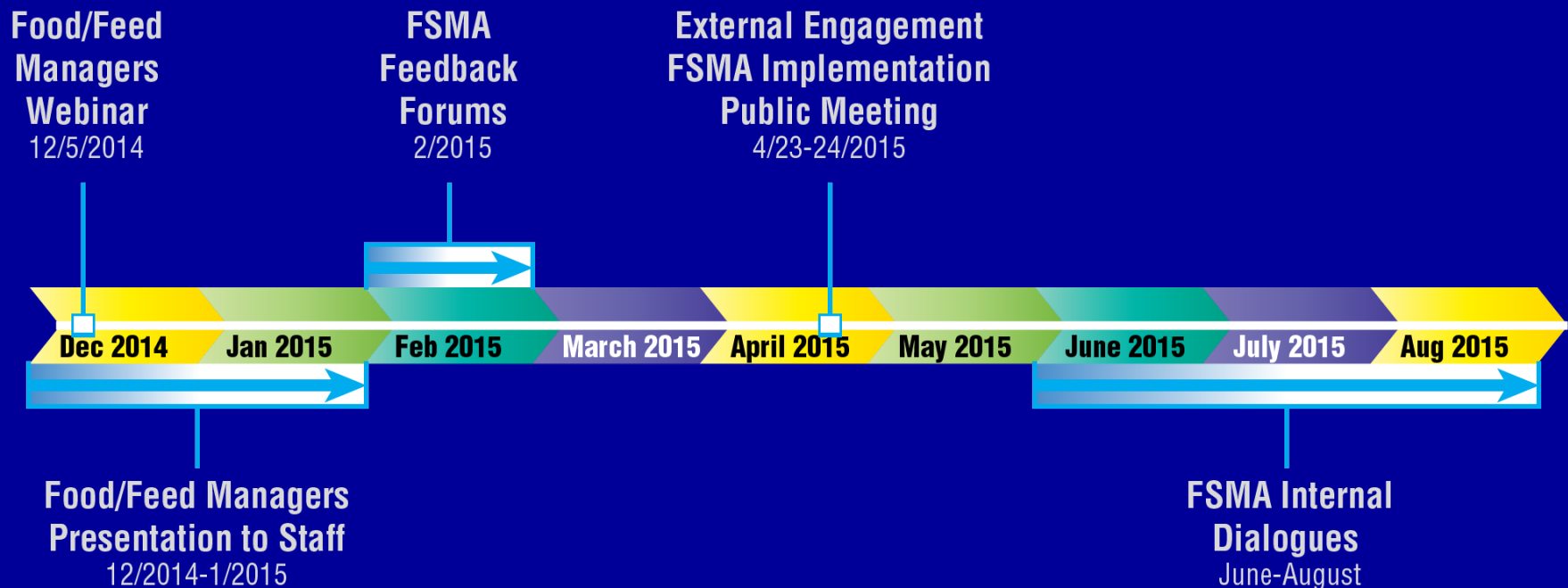
Key Implementation Principles

Accountability / Stakeholder Engagement

- Develop meaningful public health/performance metrics to measure success
- Recognize the role of the marketplace in influencing and expanding industry compliance with FSMA rules, i.e., leverage with private/public third party audit system
- Work closely with industry, government agencies, academia, and other key stakeholders/partners

FSMA Internal Communication Strategy

Internal engagement with FDA Food and Feed Safety Staff is an integral component of FDA's FSMA implementation efforts



On-going FSMA Chats – monthly broadcasts to FDA & State Food and Feed Safety Staff

FSMA Phase 3 Outcome Measures Integration Workgroup Coming soon...

Phase 3 Outcome Measures Integration Work Group Scope

- Transition FSMA strategic program planning frameworks and performance monitoring plans (PMP) from Phase 2 FSMA Work Groups to the Centers, ORA, other business owners
- Leverage existing quarterly performance review workgroup
- Refine measures with business owners
- Integrate FSMA performance measures into existing performance management systems, e.g., FDA-TRACK

Phase 3 Outcome Measures Integration Work group will ensure that measures move from design to operations and that FDA can report FSMA results and public health outcomes.

Phase 1

Rulemaking
Standards Setting
Guidance
Development

Phase 2

Strategic Program Planning
(SPP) Frameworks
Draft Performance
Measures & Monitoring
Plans

Phase 3

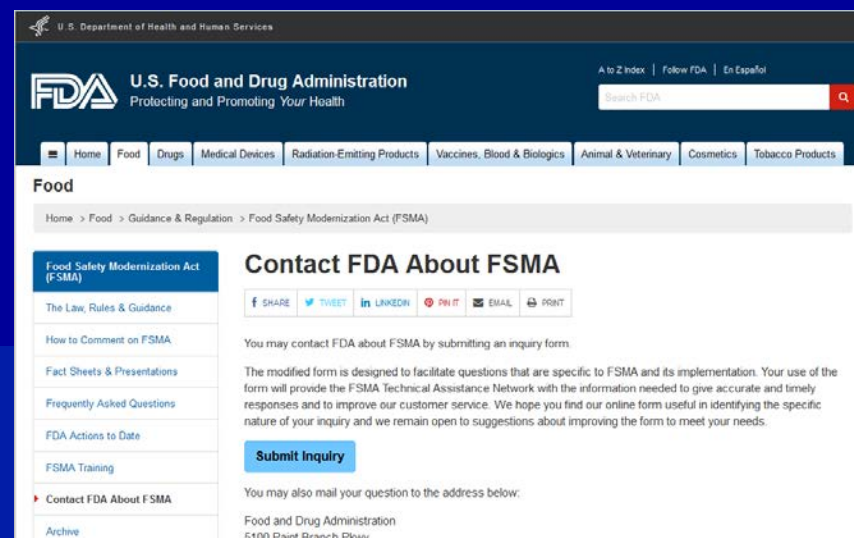
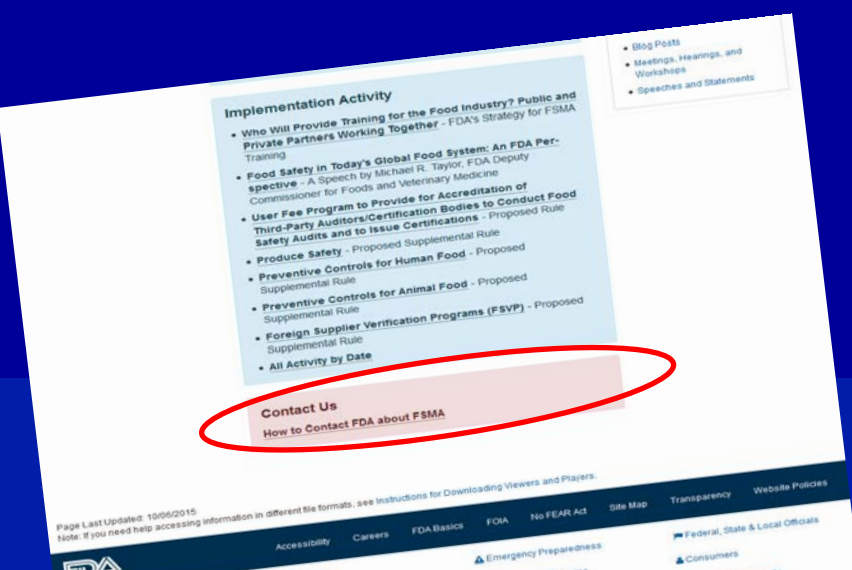
Transition SPP
frameworks, measures,
and PMPs to program
owners

Phase 3

Programs and FVM leadership
measure operational and
strategic outcomes; refresh
program activities as needed

Public Information

- Web site: www.fda.gov/fsma
- Subscription feature available
- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us



Thank You For Your Attention!